K052725
1 of 2

510(k) Summary

DEC 2 8 2005

Certol Intl., LLC
6120 E. 58th Avenue
Commerce City, CO 80022
303-799-9401 Phone
303-799-9408 Fax
Contact: Steve Cassinis
September 28, 2005

Trade Name: ProTector™
Needle Sheath Prop

Common Name: Disposable One-Handed Recapper

Classification: 21 CFR 880.5570

Product Code: FMI

This product is substantially equivalent to the legally marketed Bull's Eye Disposable Needle Recapping Aid manufactured by Hunter Research Laboratories, Inc., Denver, Colorado.

The ProTector™ Needle Sheath Prop is a disposable, non-sterile, one-time use device that can be used to safely uncap and recap needles using a one-handed technique. The ProTector™ facilitates and meets OSHA's Bloodborne Pathogens requirement to promote reduction in accidental needle sticks. Use of the ProTector™ discourages leaving the needle unsheathed on an instrument tray. The device is specifically designed to capture the needle cover/cap and hold it in the ready position.

The ProTector™ is manufactured using a premium grade rectangular paper board card. The sheathed needle cap is inserted into the targeted hole up to the cover hub, securing the needle cover firmly in the ProTector™. The targeted hole is designed as a flexible press-fit to accommodate all sizes of needle protector cover up to 3/8" OD which accommodates most needle covers on the market.

After the needle and cover is inserted into the ProTector™, it is now in the ready position to be able to safely withdraw the needle. The rectangular shape of the ProTector™ allows the needle cover to be propped on the tray in a ready position for recapping using a one-handed technique.

Indications for Use:
ProTector™ Needle Sheath Prop is a disposable, non-sterile device that can be used to safely uncap and recap needles using a one-handed technique. ProTector™ Needle Sheath Prop facilitates OSHA requirements by reducing the possibility of accidental needle sticks and discourages leaving the needle unsheathed on the tray. The Prop is autoclavable for one-time sterile tray set-up. It holds the cap securely in the ready position.

K052725
2 of 2

The ProTector™ has the same technological characteristics and material construction as the Hunter Research Bull's Eye Recapping Aid. Both products are constructed of paper board material with a variable press-fit target hole in the card. The Certol design is a rectangle which allows the loaded needle cover to be propped on the dental or medical tray. The Bull's Eye is an octagon shape but the feature to prop the cover in the ready position is the same. Both units may be autoclaved by the user.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 8 2005

Certol International, LLC
C/O Mr. Lewis Ward
President
L.W. Ward and Associates, Incorporated
4655 Kirkwood Court
Boulder, Colorado 80301

Re: K052725
Trade/Device Name: ProTector™Needle Sheath Prop, Disposable One-Handed Recapper
Regulation Number: 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: FMI
Dated: December 9, 2005
Received: December 15, 2005

Dear Mr. Ward:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

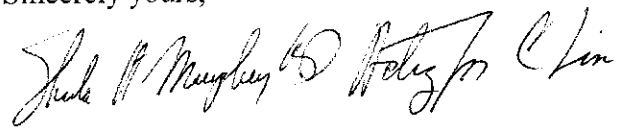
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K052725

1 of 1

INDICATIONS FOR USE

510(k)

Device Name: ProTector™ Needle Sheath Prop, Disposable One-Handed Recapper

Indications for Use:

ProTector™ Needle Sheath Prop is a disposable, non-sterile device that can be used to safely uncap and recap needles using a one-handed technique. ProTector™ Needle Sheath Prop facilitates OSHA requirements by reducing the possibility of accidental needle sticks and discourages leaving the needle unsheathed on the tray. The Prop is autoclavable for one-time sterile tray set-up. It holds the cap securely in the ready position.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-the-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

12/14/05

K 052725